K093842

510(k) Summary of Safety and Effectiveness
1.5T and 3.0T General Purpose Flex Coils

MAR - 5 2010

Submitted By:	Invivo Corporation 3545 SW 47TH Ave. Gainesville, FL 32608
Date:	December 14, 2009, revised February 8, 2010
Contact Person:	Elizabeth Wheeler, Regulatory Affairs Engineer Tel: (352) 336-0010, ext 164 Fax: (352) 336-1410
Proprietary Name:	1.5T and 3.0T 8-channel General Purpose Flex Coils
Common Name:	Coil, Magnetic Resonance, Specialty
Classification Name and Reference:	21 CFR 892.1000, A magnetic resonance diagnostic device, for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance, class II.
Device Product Code and Panel Code:	MOS / Radiology / 90

Device Description:
The design of the 1.5T and 3.0T 8-channel General Purpose (GP) Flex Coils are based on design features of the predicate device, 1.0T/1.5T/0.5T GE Quad/Phase Array Abdominal Coil. The GP Flex Coils is designed as receive only for high resolution diagnostic imaging of regional structures of the musculoskeletal hip, knee, foot, chest, and pelvis. The GP Flex Coils are manufactured of materials that are similar to those used to manufacture the predicate device.

Indications for Use:
The coil is indicated for use on the order of a physician, in conjunction with Philips 1.5T and 3.0T MR scanners as an accessory to produce images of the hip, knee, ankle, chest, and pelvic regions, as an aid to diagnosis.

Technological Characteristics:
The fundamental scientific technology of a radio frequency (RF) coil is that the coil receives radio frequency signals from the tissue of interest.

The fundamental scientific technology of the subject device described in this submission has not been altered from the predicate device.

Substantial Equivalence Information:
When compared to the predicate device, 1.0T/1.5T/0.5T GE Quad/Phase Array Abdominal Coil - K954190, cleared 11/20/95, substantial equivalence is based on similarities in design features, overall indications for use, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR - 5 2010

Ms. Elizabeth Wheeler
Regulatory Engineer
Invivo Corporation
3545 SW 47th Ave
GAINESVILLE FL 36208

Re: K093842
Trade/Device Name: 1.5T and 3.0T General Purpose Flex Coils
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: February 8, 2010
Received: February 12, 2010

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

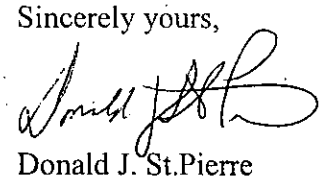
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K093842

Indications for Use

510(k) Number (if known):

Device Name: 1.5T and 3.0T General Purpose Flex Coils

Indications for Use:

The coil is indicated for use on the order of a physician, in conjunction with Philips 1.5T and 3.0T MR scanners as an accessory to produce images of the hip, knee, ankle, chest, and pelvic regions, as an aid to diagnosis.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ ODE

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093842